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Internet Pharmacies:
Regulatory Problems and Potential Solutions

Cheryl M. Teng

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Are you feeling overweight? Is your hairline receding? Maybe Meridia and Propecia are the answer for you! Too embarrassed to go to the doctor? Too busy to go to the doctor? Too busy to stand in line at a pharmacy? No problem. With the click of your mouse and a credit card number, you can order pharmaceuticals over the Internet and have them delivered to your door...

Internet pharmacies are a relatively recent phenomenon. In January 1999, the Internet hosted about 30 Internet pharmacies, and by July of that year, over 400 such pharmacies had appeared.¹ Today, the number of Internet pharmacies may be as high as 1,000.² Unfortunately, the actual number of Internet pharmacies is unknown due to the anonymity of the Internet. Internet addresses can be easily created or removed, and

¹*Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO REPORT TO CONGRESSIONAL REQUESTERS, at 3 (October 2000) [Hereinafter *GAO Report*].

²Skidmore, Sarah, *Officials Warn Those Ordering Prescription Drugs Online*, THE FLORIDA TIMES, February 13, 2001, at F-1.

many Internet pharmacies use multiple web sites or portals to attract customers.³ Despite the difficulty in counting Internet pharmacies, the real number can be expected to increase due to the profit opportunities in the pharmaceutical market. Internet pharmacies generated over \$100 million in sales in 1999, and experts predict that sales will reach \$1 billion in 2002 and reach \$15 billion by 2004.⁴

Internet pharmacies do offer many benefits to U.S. consumers. These benefits include access to drugs for the disabled, for whom a trip to a traditional pharmacy is difficult; the ability to shop 24 hours a day; and privacy for those who don't feel comfortable discussing their medical conditions in public. The online option can be cheaper since it eliminates several layers of overhead. Indeed, some legitimate Internet pharmacies are selling prescription drugs online for up to 30% less than what is charged at traditional pharmacies.⁵ Besides added convenience and lower costs, Internet pharmacies can increase consumer access to relevant medical information. Hyperlinks from Internet pharmacy webpages can provide customers with references from other sources much more easily than a traditional pharmacy.

With all these benefits, some may view the expected growth in Internet pharmacies to be positive revolution for the healthcare industry. But embracing the growth of Internet pharmacies without immediately and thoroughly addressing regulatory loopholes in the state and federal laws which apply to Internet pharmacies could have terrible consequences for the health of the American public. Internet pharmacies should not be regulated (or free from heavy regulation) like other forms of e-commerce since improperly dispensed medications could cause drug interactions, allergic reactions, and even death.

³GAO Report, *supra* note 1, at 10.

⁴Chambliss, Lauren, *Rogue Online Drugs Sales are Not What the Doctor Ordered*, EVENING STANDARD, March 11, 2002, at 41.

⁵Dana, Miller, *Trends in Self-Care*, PATIENT CARE, August 15, 2000, at 57.

This paper will analyze the growing problem “rogue” Internet pharmacies—Internet pharmacies that conduct illegal or unsafe prescribing and dispensing practices that endanger the health of the customers they serve. SECTION I will describe the different categories of Internet pharmacies and distinguish the practice of legitimate Internet pharmacies from those of rogue Internet pharmacies. SECTION II will discuss the dangers customers face by ordering from rogue Internet pharmacies. SECTION III will address the currently regulatory regime for domestic Internet pharmacies. SECTION IV will address the currently regulatory regime for foreign Internet pharmacies. Finally, SECTION V will analyze recent proposals to more effectively curtail the illegal practice of domestic and foreign Internet pharmacies.

I. Types of Internet Pharmacies.

There are four basic categories of online pharmacies that cater to American consumers. The focus of this paper will be on the rogue Internet pharmacies, which encompass the last three categories of online pharmacies. Some estimate that rogue sellers outnumber legitimate Internet pharmacies by a ratio of over 60 to 1.⁶

Type 1: Legitimate. Many companies have established “legitimate Internet pharmacies.” These businesses are located in the United States. They require the consumer to obtain and submit a prescription from a licensed physician. The consumer can transfer a prescription from another pharmacy, mail in a new prescription, or have his physician submit the prescription by fax or telephone. Before dispensing any drugs, the Internet pharmacy verifies that a licensed physician has actually issued the prescription. These types of Internet pharmacies operate similar to traditional pharmacies, and many are extensions of traditional, brick-and-mortar pharmacies.⁷ Thus, these types of sites are not controversial.

⁶Otompke, John. *Internet Likely to Open Brave New World in Global Pharmaceuticals Trade*, MEDICINE & HEALTH, October 9, 2000, at S1.

⁷GAO Report, *supra* note 1, at 10.

Type 2: Borderline-Foreign. Some Internet pharmacies operate in certain foreign countries, particularly Canada, with regulations on distribution of pharmaceuticals that are similar to those in the U.S. These sites require customers to submit a U.S. doctor's prescription and fill out a basic questionnaire. After a Canadian doctor reviews the information, he may then write a Canadian prescription for the same medication and dose. The Internet pharmacy then fills the order and ships it to the consumer.⁸ Although these practices are permitted under Canadian law, these sites are controversial since the safeguards imposed by Canadian government to ensure the quality of pharmaceuticals may not be comparable to those imposed by the U.S. Food and Drug Administration (FDA).⁹

Type 3: Borderline-Domestic. Other Internet pharmacies offer online medical consultation services together with prescription-filling services. Typically, the consumer will fill out a simple online questionnaire about his diagnosis, medical profile and history, and current medication usage. The questionnaire is reportedly reviewed by a physician, after which the physician may issue a prescription which will be filled by the online pharmacy. The cost for the physician review ranges from \$35 to \$85.¹⁰ These sites are controversial. Critics contend that an online questionnaire is not a sufficient substitute for a traditional patient-physician relationship established through an in person examination.

Type 4: Illicit-Foreign. The most alarming category of Internet pharmacies are those that sell pharmaceuticals without requiring a prescription. All the consumer needs to do is choose the drug he desires and complete the purchase with a credit card. These types of pharmacies offer FDA-approved medications as well as medications that have not been approved by the FDA. These sites are the most controversial. Pharmacies in this category are primarily foreign-based pharmacies that are able to evade the jurisdiction of U.S.

⁸Allison, Wes, *Prescription for Drug Prices: Canada?*, ST. PETERSBURG TIMES, January 7, 2002, at 1A.

⁹Id.

¹⁰GAO Report, supra note 1, at 10-11.

federal and state laws.¹¹

III. Who Buys From Rogue Internet Pharmacies?

Although rogue Internet pharmacies may be engaging in illegal and unsafe practices, they may nevertheless be offering a resource that has a net benefit to some individuals in society. In analyzing proposals to regulate and eliminate rogue Internet pharmacies, it is useful to consider the different categories of individuals who are purchasing or are likely to purchase from these web sites. There are three basic types of customers: those who wish to procure (1) lifestyle drugs, (2) unapproved drugs, or (3) cheaper drugs.

Lifestyle drugs. Unlike legitimate Internet pharmacies that operate like a traditional pharmacy and offer a large spectrum of pharmaceutical products, many rogue Internet pharmacies specialize in or limit their range of products to “lifestyle drugs.” Lifestyle drugs are pharmaceuticals that are taken not to relieve or cure a medical condition, but are taken instead to improve the quality of life of the person taking it.¹² Drugs generally considered as lifestyle drugs include Viagra (for impotence), Propecia (for hair loss), and Xenical (for obesity). Individuals may turn to rogue Internet pharmacies to purchase lifestyle drugs for several reasons. Many people may be embarrassed about going to a physician to address the problems for which the lifestyle drug is prescribed; they can avoid such embarrassment by using an online pharmacy that will write a prescription based on an online questionnaire or one that does not require a prescription at all. Some people may mistakenly believe that since these pharmaceuticals are not for the treatment of serious

¹¹Id. at 11.

¹²One should note that there is dispute about what constitutes a medical condition that needs treatment and what is just cosmetic, discretionary or even unnecessary.

medical problems, there is no need to visit a doctor to obtain a prescription. Or, people may turn to rogue Internet pharmacies because their doctor has turned them down and they want the drug anyway.¹³ Individuals probably do not turn to these sites to save money. Ordering these medications from rogue Internet pharmacies often ends up costing more than going to a doctor for an exam and then filling the prescription at a traditional pharmacy.¹⁴ Although a Consumer Reports survey showed that drugs such as antibiotics, antihistamines and antidepressants were on average cheaper online, a University of Pennsylvania study found that lifestyle drugs, such as Propecia and Viagra, are more expensive if purchased online.¹⁵ Moreover, the cost differential between legitimate online pharmacies and rogue Internet pharmacies seems to be quite large. For example, a three-month supply of Propecia costs \$128 (including \$2 shipping) from drugstore.com, a legitimate Internet pharmacy; \$295 (including \$75 consultation fee and \$18 shipping) from pillstore.com, an Internet pharmacy that conducts online medical consultations; and, \$300 (including \$45 shipping) from pillen2000.com, a foreign-based Internet pharmacy that does not require a prescription.¹⁶ Assuming that the individual does not have health insurance or prescription drug insurance, a physician appointment would have to cost over \$167 to make purchasing Propecia from one of these rogue Internet sites cost-effective. In addition, comparing costs for a one-year supply of the medication makes the overpricing stark. Assuming, again, that an individual does not have health or prescription drug insurance, the cost of visiting a physician during the year for the prescription would have to exceed \$668 to make the purchasing Propecia from one of these rogue Internet sites cost-effective.

Unapproved drugs. Many rogue Internet pharmacies are located in foreign countries. This gives Americans

¹³Ignelzi, R.J., *Online Drug Buyers Gamble with More Than Credit Cards*, WASHINGTON WIRE, August 27, 2001.

¹⁴Ignelzi, supra note 13.

¹⁵Osher, Chris, *State May Force Druggists Online to Take Bitter Pill*, THE ARKANSAS DEMOCRAT GAZETTE, May 14, 2000, at A1.

¹⁶Drugstore.com (visited March 24, 2002) <<http://drugstore.com>>; Pillstore.com (visited March 24, 2002) <<http://pillstore.com>>; Pillen2000.com (visited March 24, 2002) <<http://Pillen2000.com>>.

direct access to foreign pharmaceutical markets whereby consumers can purchase medications that are not available in the United States. The access to drug therapies that have not been approved by the FDA may benefit individuals who are looking for a cure to a serious medical problem and for whom FDA-approved drugs have been unsuccessful.

Cheaper drugs. Access to foreign pharmaceutical markets also allows consumers to save money on some FDA-approved drugs. The United States does not impose price controls pharmaceuticals sold within its borders. In contrast, most other industrialized countries—including Canada, France, Japan and Germany—do impose price controls. A 1994 study that compared a “basket” of widely prescribed drugs across countries found that prices were on average 60% higher in the U.S. compared to other countries.¹⁷

The necessity of access to lower-cost pharmaceutical markets is especially relevant for those individuals who do not have prescription drug insurance. In 1996, about 23% of Americans under age 65 and 27% of Medicare beneficiaries (those over age 65) had no insurance coverage for prescription drugs.¹⁸ A recent survey found that 30% of the uninsured under age 65 said they did not fill a prescription because of cost, compared to 12% of the insured.¹⁹ Access to foreign Internet pharmacies may make medications affordable to many of these individuals who would otherwise go untreated.

Buying medicines from foreign Internet companies can also be cheaper for individuals that do have prescription drug insurance coverage. Some consumers have found that buying some drugs from foreign countries is cheaper than paying what is left after insurance pays its part of the U.S. price.²⁰ Indeed, in a typical PPO insurance plan, the participant must reach a certain deductible (perhaps \$1000 or higher) before prescriptions are covered. And even once the deductible is covered, most plans require “coinsurance” payments—often up

¹⁷Stanton, Jerry. *Lessons for the U.S. from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT’L L. 149, 165 (2000).

¹⁸The Kaiser Family Foundation and the Sonderegger Research Center, *PRESCRIPTION DRUG TRENDS—A CHARTBOOK UPDATE*, 3-4 (Nov. 2001).

¹⁹*Id.* at 5.

²⁰Gingerich, Jason W., *Web Offers May Ways to Get Drugs*, SOUTH BEND TRIBUNE, October 30, 2000, at B8.

to 20% to be paid by the patient.

II. Dangers of Rogue Internet Pharmacies

Online pharmaceutical sales present potential for abuse and misuse at both the consumer and vendor levels. The dangers to consumers include self-diagnosis and self-medication, lack of sufficient medical review, and substandard products.

Self-diagnosis and self-medication. Since some Internet pharmacies allow customers to purchase pharmaceuticals without a prescription, this allows customers to self-diagnose and self-medicate. Self-diagnosis and self-medication are dangerous because consumers lack safeguards that are present in the traditional distribution channel for pharmaceuticals which informs patients on proper dosage, possible side effects, and drug interactions. Some conditions allayed by drugs may have underlying causes that are not obvious and which can only be diagnosed by a thorough medical examination. For example, a person may purchase Viagra to treat impotence, but the cause of the impotence could be a pituitary tumor, diagnosed only through a physical exam and laboratory tests.²¹ In the worst case scenario, self-medication can result in death. For instance, in March 1999, a 52-year old man with a family history of heart disease died of a heart attack after buying Viagra from an online site that required no prescription.²² In November 1999, a man in his 20's who was suffering from chronic depression died of an accidental overdose from ingesting controlled sub-

²¹ *Prescription for Trouble*, CONSUMER REPORTS, February 2001, at 19.

²² Ignelzi, *supra* note 13.

stances obtained from a overseas pharmacy without a prescription.²³ And although a physician-obtained prescription does not guarantee that there is a proper diagnosis or proper use of the medication, the risk of negative outcomes such as harmful drug interactions, contra-indications, allergic reactions or improper dosing is greatly lower.

Flawed Review Process. The companies that require customers to fill out a questionnaire to obtain a prescription may seem safer than those that require no prescription at all, however, it is possible that a licensed physician may never review the information. There are numerous stories about people who have been able to obtain drugs online posing as animals, dead people, young children, or as patients with clear contra-indicated conditions. One news reporter, investigating the dangers of online prescribing, procured Viagra for a cat from one website. He truthfully filled out the questionnaire and stated that the patient stood 6 inches tall, weighed 15 pounds and was neutered. The reporter was also able to procure Viagra from another website for an imaginary person who revealed clear contra-indications on the questionnaire—heart trouble and current use of nitrate medicines.²⁴ Clearly in both cases, there was no medical review of the questionnaires.

Even if the questionnaire is actually reviewed, there is often no way to assure that this review process is sufficient. Many rogue Internet pharmacies do not disclose associated physicians or pharmacists, and thus there is no way to check the credentials of the healthcare professionals or confirm whether healthcare professionals are used at all. Individuals not licensed to prescribe or sell prescription drugs can easily design a website that appear to represent legitimate a pharmacy.²⁵ Where a licensed physician does review the questionnaire, there is more room for error than if the physician actual sees the patient. Moreover, there

²³*Continuing Concerns over Imported Pharmaceuticals: Hearings Before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce*, 107th Cong. at 25 (2001) [Hereinafter *Hearings 2001*] (testimony of Edwin and Helen Rode).

²⁴Yeoman, Barry, *Drugs Online the New Danger*, LADIES HOME JOURNAL, May 1, 2001.

²⁵*Enforcing the Law on Internet Pharmaceutical Sales: Where are the Feds?: Hearing Before the Subcommittee on Oversight and Investigations of the House Committee on Commerce*, 106th Cong. at 15 [Hereinafter *Hearings 2000*] (prepared statement of William K. Hubbard, Senior Associate Commissioner of the FDA).

is the possibility that the terms used in the questionnaire may be beyond the technical comprehension of the consumer, and since many forms are already filled out with the “correct” answers necessary to obtain a certain pharmaceutical, contra-indicated conditions may be missed.²⁶

Additionally, there is no mechanism to ensure that consumers are answering questions truthfully; most rogue Internet pharmacies make no effort to confirm the accuracy of the questionnaires. For example, when one woman ordered the diet drug Xenical, the order was originally denied because her weight entered was too low. No problem: she simply increased her weight in the questionnaire, and the order was approved.²⁷ Such deception would not have been possible in a traditional physician-patient relationship.

Substandard Products. One congressman has likened buying drugs online to the “healthcare equivalent of trick-or-treating in a bad neighborhood.”²⁸ A U.S. Customs official likened it to “playing Russian roulette with your life.”²⁹ Even if the individual has a diagnosed medical problem and has obtained a prescription from a physician, there is still the risk that the products procured will be substandard. This is especially a problem encountered by purchasing pharmaceuticals from a foreign-based pharmacy.

In the United States, the Food, Drug and Cosmetic Act (FDCA) prohibits the manufacture and distribution of misbranded and adulterated drugs and requires drugs to be handled in ways that prevent them from being contaminated. Foreign countries may not have or enforce similar regulations and the risk of substandard goods is high. Some estimate that the percentage of counterfeit and substandard imported drugs could be as high as 25% of the imports.³⁰

Although a foreign website may advertise the sale of FDA-approved, U.S.-made medications, such represen-

²⁶Yeoman, *supra* note 24.

²⁷*Id.*

²⁸*Hearings 2000*, *supra* note 25, at 2 (statement of Congressman Fred Upton).

²⁹Ignelzi, *supra* note 13.

³⁰*Hearings 2001*, *supra* note 23, at 20 (prepared statement of Congressman Bobby Rush).

tations may be false. Even if the customer receives a product that looks identical to one purchased in the United States, the product may be counterfeit. The production of counterfeit medications is pervasive outside the United States. According to one pharmaceutical industry expert, “counterfeiters are able to produce labels that are virtually indistinguishable from the true labels.”³¹ These counterfeit medications may contain expired ingredients, adulterated ingredients, or dangerous sub-potent or super-potent ingredients.³² And, there is no guarantee that these products contain any active ingredients at all or that they are manufactured and packaged under sanitary conditions. One Internet pharmacy based in a vermin-infested warehouse in Bangkok had kids stuffing bags with “Viagra” pills made from Vodka paste and which were strewn all over the floor.³³ Drugs ordered from Internet pharmacies in countries with strict regulations like Canada also do not assure drugs meet the FDA standards for quality. Canada could become an entry point for substandard foreign drugs seeking access to the U.S. market and the FDA cannot assure that Canadian quality controls are sufficient.³⁴

III. Current Regulatory Scheme for Domestic Internet Pharmacies.

With all the dangers posed by prescribing and dispensing practices of rogue Internet pharmacies, something must be done to curtail these activities. There are four potential sources of action that could protect consumers from the unethical and unsafe practices of Internet pharmacies located within the United States: private actions, industry self-regulation, state action and federal action.

Private Actions. If consumers could file malpractice or other private actions against Internet pharmacies, this could deter Internet pharmacies from engaging in dangerous prescribing and dispensing practices. Unfortu-

³¹*Hearings 2001*, supra note 23, at 158 (statement of John D. Glover, Vice President of Corporate Security, Bristol-Meyers Squibb).

³²*Id.*

³³Ignelzi, supra note 13.

³⁴Allison, supra note 8.

nately, due to the use of “clickwrap” waivers, consumers who are harmed by the medications they purchase may not have legal recourse against rogue Internet pharmacies. Clickwrap provisions are a system used in e-commerce that prevent a user from carrying out an action on the website until they have agreed to the terms and conditions of use. The terms and conditions of use generally pop up in a new window and allow a user to signal assent with an on-screen click. If the user does not agree to the terms and conditions, the website is designed so that the visitor cannot proceed any further.

Many rogue Internet pharmacies use clickwrap waivers to disclaim liability. For example, one website requires a consumer to waive “any and all liability associated with or arising from the physician consultation or from the medical, physical, behavioral or other effects of any medication that may be ordered, prescribed or purchased as a result of the physician consultation.”³⁵ The 1999 GAO study of Internet pharmacies revealed that only rogue Internet pharmacies use liability waivers. The GAO found that of 111 identified pharmacies that require a prescription, 0 used such waivers; of 54 identified pharmacies that issue prescriptions after reviewing questionnaires, 45 (or 83%) used such waivers; of 25 identified pharmacies that do not require a prescriptions, 18 (or 72%) used such waivers.³⁶ Internet pharmacies that engage in high-risk prescribing and dispensing practices are counting on the clickwrap waivers to protect them from consumer liability.

Unfortunately, courts are likely to enforce clickwrap waivers against individuals who purchase from rogue Internet pharmacies. Some consumer rights proponents have argued that clickwrap agreements should not be upheld, since consumers do not read such boilerplate.³⁷ Nevertheless, with respect the clickwrap agreements as they apply to e-commerce in general, the trend in case law has been to enforce such agreements as long as the customer’s assent is sufficiently affirmative and as long as the contract is not unconscionable.³⁸ If

³⁵E-scripts-md.com, *Patient Responsibility Statement and Statement of Informed Consent* (viewed March 2, 2002) <http://www.e-scripts-md.com/patient_responsibility.asp>.

³⁶GAO Report, *supra* note 1, at 10.

³⁷Vartanian, Thomas, Guest speaker, Exploding Internet Class, Harvard Law School (Feb. 20, 2000).

³⁸Gray, Megan and Brian Ross, *Contracts Drafting Stronger Clickwrap Agreements*, THE INTERNET NEWSLETTER 6.6, Sept. 2001, at 1 – 6.

the customer affirmatively clicks on an “I Agree” button, the customer is typically deemed to manifest the necessary asset.³⁹ There has only been one case on clickwrap agreements in the context of Internet pharmacies. Recently, the Supreme Court of Kansas held that a clickwrap agreement that released an Internet pharmacy from all consumer liability was not unconscionable under state law.⁴⁰ According to the Court, there must be some element of deceptive bargaining.⁴¹ Since nothing was misrepresented by the website and all drugs furnished were authentic, the agreement was valid.⁴² One commentator has noted that courts have a tendency to override waivers in healthcare settings, and as a result, has predicted that clickwrap agreements are unlikely to be upheld in the context of Internet pharmacies.⁴³ Whether other courts will follow the reasoning of the Supreme Court of Kansas remains to be seen. Given the trend toward enforcing clickwrap agreements in e-commerce, other courts may follow the lead of the Kansas.

Industry Regulation. Industry self-regulation is another potential form non-governmental regulate Internet pharmacies. The National Association of Boards of Pharmacy (NABP) has made an attempt an attempt at industry self-regulation.⁴⁴ In 1999, NABP developed a program called Verified Internet Pharmacy Practice Sites (VIPPS) to help customers identify if an Internet pharmacy is legal and is maintaining certain quality standards. To qualify for the VIPPS seal, which an online pharmacy can post on its web site, an online pharmacy is required to satisfy 17 Internet pharmacy criteria. These criteria include complying with the licensing requirement of each state in which the pharmacy dispenses medications, passing an on-site visit from the VIPPS inspection team at the pharmacy’s headquarters, meeting certain levels of security and integrity for its medication, information and services, and offering immediate access to a pharmacist so that

³⁹Id.

⁴⁰Kansas v. Confimed.com, 38 P.3d 707, 712 (Kansas Sup. Ct. 2002).

⁴¹Id. at 713.

⁴²Id. at 714.

⁴³Chuang, Chester, *Is there a Doctor in the House? Using Failure to Warn Liability to enhance the Safety of Online Prescribing*, 75 N.Y.U. L. Rev. 1452, 1488 n.18 (2000).

⁴⁴The NABP was established in 1904 to assist state licensing boards in developing, implementing, and enforcing uniform standards to protect the Public Health. Pharmacy boards from fifty states, the District of Columbia, three U.S. territories, nine Canadian provinces, and four Australian states make up the association membership.

customers can report any medication problems. In addition, they must provide a link on their web site to the NABP so that consumers can report any problems they might encounter with the web site.⁴⁵ To date, only fourteen Internet pharmacies have been awarded VIPPS certification.⁴⁶ While such certification may help customers who are trying to locate a legitimate Internet pharmacy, because it is not a mandatory system, it does nothing to reduce the supply of Internet pharmacies that cater to customers who wish to obtain a pharmaceutical without a prescription obtained from a traditional physician-patient relationship.

State Regulation of Domestic Internet Pharmacies. Since private actions and industry self-regulation have not been sufficient to regulate Internet pharmacies, government regulation is necessary. Most enforcement actions against rogue Internet pharmacies and associated physicians located within the United States have come from state action. Internet case law indicates that the proper jurisdiction for legal action resides in the state where the purchaser lives, not the location of the Internet business.⁴⁷ Thus, state attorney generals can file lawsuits against online pharmacies outside the state as well as those in their jurisdiction.

State attorneys general have based actions on a variety of legal theories, seeking injunctions and civil penalties. Some states have filed lawsuits against Internet pharmacies dispensing pharmaceuticals to its residents without being licensed by its state board of pharmacy. Thirty-nine states require pharmacies to be licensed in the state in which they are based, as well as in each state where the patients reside.⁴⁸ Some states have filed lawsuits against Internet pharmacies for violating state consumer protection laws by giving the false impression that completing an online questionnaire is comparable to a doctor's examination.⁴⁹ Other states have charged individual physicians who prescribe medications based on questionnaires rather than conducting physical evaluations with violating state statutes prohibiting "unprofessional conduct" or violating state

⁴⁵National Association of Boards of Pharmacy, *VIPPS Criteria* (last modified Nov. 29, 1999) <<http://www.nabp.net/vipps/consumer/criteria.asp>>.

⁴⁶National Association of Boards of Pharmacy, *Verified Internet Pharmacies List* (viewed April 1, 2002) <<http://www.nabp.net/vipps>>.

⁴⁷*Zippo Mfg. Co. v. Zippo Dot Com*, 952 F. Supp. 1119 (D. Pa. 1997) (holding that the defendant's conduct of electronic commerce with Pennsylvania residents constituted "purposeful availment" of doing business in Pennsylvania).

⁴⁸Kearney, Kerry and Celia Santander, *Telemedicine: Evolving into Cyberspace*, HEALTH LAWYER, April 2001.

⁴⁹Goetz, John and Donald Lund, *What the Law Allows*, PHARMACEUTICAL EXECUTIVE, August 1, 2000, at 76.

medical practice laws.⁵⁰ The American Medical Association (AMA) has taken the position that the issuance of a prescription based solely on an online questionnaire for the patient does not meet the appropriate standard of care and is not a valid prescription.⁵¹ The State Federal of Medical Boards (FSMB) has taken the position that prescribing of medication by physicians based solely on an electronic medical questionnaire is outside the bounds of professional conduct.⁵² Nevertheless, whether an online questionnaire can result in a valid prescription may vary across states, since the applicable standard of care is determined by each states' medical practice laws.

Despite state efforts to prosecute rogue Internet pharmacies, these actions, without new federal and state legislation, will not be sufficient to curb illegal activities by domestic Internet pharmacies. Many state regulators and agencies lack the resources and expertise necessary to investigate and prosecute violations.⁵³ State regulators have encountered difficulty in identifying and locating the physicians, pharmacists and principals involved.⁵⁴ In absence of direct physical injury to customers, state officials may not see these cases as priorities given limited resources.⁵⁵ Even when a state successfully prosecutes an out-of-state Internet pharmacy and its associated physicians and pharmacists and stops them from prescribing and dispensing drugs to residents of that state, the court action applies only in that state. And, if a state brings an action against an Internet pharmacy located within its borders, the pharmacy could simply re-open operations in another state. This jurisdictional limitation also prevents state medical and pharmacy boards from effectively curbing rogue Internet pharmacies. State medical and pharmacy boards can also impose sanctions upon a doctor or pharmacist who is engaging in unethical or illegal activities. However, if a board comes

⁵⁰Id.

⁵¹American Medical Association, *Internet Prescribing*, (visited April 12, 2002) < <http://www.ama-assn.org/meetings/public/annual99/reports/onsite/bot/rtf/bot35.rtf>>

⁵²Federation of State Medical Boards, *The Report on the Special Committee on Professional Conduct and Ethics*, § IV, *Internet Prescribing* (visited April 16, 2002) <<http://www.fsmb.org>>.

⁵³Cleland, Richard L., *Cross-Border Telemedicine: an Uncertain Future*, SAINT LOUIS UNIVERSITY LAW JOURNAL 149, 154 (Winter 2002).

⁵⁴*Hearings 2000*, supra note 25, at 11 (statement of William Hubbard).

⁵⁵Cleland, Richard L., *Cross-Border Telemedicine: an Uncertain Future*, SAINT LOUIS UNIVERSITY LAW JOURNAL 149, 154 (Winter 2002).

across a doctor or pharmacist licensed in another state and dispensing prescription drugs to residents in the board's state, the board has no jurisdiction to impose sanctions. The board is limited to sending warnings or lodging complaints with the counterparts on the medical and pharmaceutical boards where the online pharmacy, physician or pharmacist is located.

Within the last couple years, some states have enacted legislation aimed specifically at the conduct of pharmacies conducting business over the Internet. These statutes adopt strict disclosure requirements, make VIPP certification a mandatory requirement, clarify the definition of a valid prescription, clarify the need for out-of-state pharmacies to be licensed where the customer resides, and/or impose large civil penalties or criminal sanctions for failing to comply with the statute. For example:

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The problem with these legislative actions is that they make it expensive for a legitimate online pharmacy

to operate if it has to undergo strict licensing procedures and pay licensing fees for each state. Since each state has different requirements as to the frequency of licensing fees, compliance may be difficult for Internet pharmacies. And, since each state has different requirements as to what information the Internet pharmacy must reveal on its website, this would effectively require an Internet pharmacy that wishes to serve the U.S. market to comply with the strictest state regulations. All these burdens placed upon Internet pharmacies by the new legislative actions leads to the possibility that these statutes may violate the dormant Commerce Clause.

The dormant Commerce Clause of the United States Constitution poses a significant question about the validity of state attempts to regulate Internet pharmacies through new legislation. The Commerce Clause provides: “the Congress shall have Power...To regulate Commerce...among the several States...”⁶⁵ The negative or dormant implication of the Commerce Clause prohibits state regulation that unduly burdens interstate commerce.⁶⁶

The leading case on the application of the dormant Commerce Clause to the Internet is American Libraries Association v. Pataki.⁶⁷ The case involved a New York statute that prohibited intentional use of the Internet to engage in pornographic communications deemed to be “harmful to minors.” The United States District Court for the Southern District of New York held that the New York statute was an unconstitutional intrusion into interstate commerce. It is difficult for Internet users to control access to their websites, newsgroup postings, and other communications, and fear of liability in New York might chill activities by Internet users operating legally in other states.⁶⁸ Since other states regulate pornographic communications differently, “a single actor might be subject to haphazard, uncoordinated, and even outright inconsistent regulation by states that the

⁶⁵U.S. CONST. art. I, § 8, cl. 3.

⁶⁶Goldsmith, Jack L. and Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 786 (2001).

⁶⁷American Library Association v. Pataki, 969 F. Supp. 160 (D. N.Y. 1997).

⁶⁸Id. at 177.

actor never intended to reach of possibly was unaware were being accessed.”⁶⁹ In addition, the court stated, “the Internet is one of those areas of commerce that must be marked off as a national preserve to protect users from inconsistent legislation that...could paralyze development of the Internet altogether.”⁷⁰

Taken to an extreme, the Pataki decision would invalidate every state attempt to regulate the Internet, including attempts to regulate Interstate pharmacies. Not all Commerce Clause scholars, however, would agree with such a broad interpretation of the dormant Commerce Clause. According to Jack Goldsmith and Alan Sykes, professors of law and Chicago Law School, the fact that a state Internet regulation imposes costs on out-of-state actors cannot by itself be the basis for illegality under the dormant Commerce Clause:

A more plausible interpretation of the inconsistent-regulations concern is that non-uniform state regulations might impose compliance costs that are so severe that they counsel against permitting the states to regulate a particular subject matter. At the limit, actors may become subject to different regulations to such an extent that compliance becomes effectively impossible if they are to engage in interstate commerce. Similarly, firms may become subject to regulatory requirements in one jurisdiction that accomplish no more than different regulatory requirements imposed by another jurisdiction, with the result that regulatory compliance costs increase significantly for no good reason. The same regulatory benefits could be obtained at lower cost if the states simply adopted the same policies or restated their policies in terms that allowed regulated entities to comply by choosing among the various equally effective compliance options.⁷¹

Thus, in applying the dormant Commerce Clause, the courts must apply a balancing test, and where the statute effectuates a legitimate local public interest, it should be upheld unless the burden imposed on interstate commerce is excessive relative to the local benefits.⁷²

The newly enacted state laws which attempt to regulate Internet pharmacies may or may not violate the dormant Commerce Clause, depending on whether they fail the balancing test. According to Goldsmith and Sykes, regulations that involve the out-of-state provider of real-space goods are less likely to violate the dormant Commerce Clause than those that involve the transmission of digital goods over the Internet,

⁶⁹Id. at 168.

⁷⁰Id. at 181.

⁷²Id. at 804.

since the provider or real-space goods can more easily determine where the goods are going and research and comply with local regulations.⁷³ Nevertheless, this fact is not conclusive of whether the new state laws regulating Internet pharmacies would violate the dormant Commerce Clause. If states have similar licensing requirements for health care professionals, it does seem duplicative to require them to register and pay corresponding licensing fees in each state to which they dispense medications. Indeed, the same regulatory benefits could be obtained at a much lower cost if the states simply adopted the same policies or restated their policies in terms that allowed the Internet pharmacies to comply by choosing among the various equally effective compliance options.

Federal Regulation of Domestic Internet Pharmacies. The Food, Drug and Cosmetic Act (FDCA) generally prohibits the manufacture and distribution of misbranded and adulterated drugs, and requires drugs to be labeled accurately and handled in ways that prevent them from becoming contaminated or misused. Products that qualify as prescription drugs under the FDCA can only be dispensed with a valid prescription from a licensed doctor. If a pharmacy sells drugs without a valid prescription, the products are considered “misbranded” and the pharmacy is in violation of the law.⁷⁴ Violators can be imprisoned for up to one year and fined up to \$1,000. Repeat offenders can be imprisoned for up to three years and fined up to \$10,000.⁷⁵ The FDCA applies to all pharmacies, traditional and those online. Clearly, Internet pharmacies that do not require a prescription would be selling “misbranded” drugs in violation of the FDCA. Internet pharmacies which request some medical information and pass it on to a web doctor, may or may not violate the FDCA, depending on whether the transaction constitutes a valid prescription under state law. As discussed above,

⁷³Id. at 824.

⁷⁴FDCA §§ 301, 503, 21 U.S.C. §§ 331, 353 (2002) (FDCA § 301(a) cites as a prohibited act the introduction into interstate commerce of any drug that is “misbranded.” According to FDCA § 503(b)(1)(B), a drug “shall be dispensed only...upon a written prescription of a practitioner licensed by law to administer such drug” or upon an equivalent verbal prescription which is promptly reduced to writing. If a drug is dispensed contrary to this provision, the drug shall be deemed misbranded.)

⁷⁵FDCA § 303(a), 21 U.S.C. § 333(a) (2002).

the AMA and the FSMB agree that a prescription issued solely based on an online questionnaire is not a valid prescription. But, despite the views of these associations, it is state law that governs. If the state does not attest that the prescription being written is invalid, the FDA has difficulty bringing a successful case.⁷⁶ The lack of consistent state laws on what constitutes a “valid prescription” is not the only impediment to successful FDA actions. The FDA lacks sufficient resources to deal with the problem of rogue Internet pharmacies. The FDA has expressed the same difficulty as state actors: investigations are difficult and costly because so few rogue Internet sites list addresses or identifying information.⁷⁷ These impediments may explain why, as of June 2001, the FDA actions have only resulted in five criminal convictions and no reported successful civil actions involving the sale prescription drugs without a “valid prescription.”⁷⁸

Another possible source of federal action is through the Federal Trade Commission Act (FTCA) which implicates activities which may be “misleading” or “unfair,” including Internet pharmacies that make false or misleading claims about the products or services they provide. For example, in FTC v. Rennert, the FTC claimed that the defendant’s Internet pharmacy falsely represented that the customers were served by a clinic with physicians and an on-site pharmacy.⁷⁹ In reality, the Internet pharmacy employed only one out-of-state physician to review the medical questionnaires. Other possible representations, if false or misleading, may violate the FTCA include a representation that (1) the product is safe, (2) that an online consultation is equivalent to a physician examination, or (3) that a pharmacy is licensed to dispense medications in the customer’s state. But, despite these possibilities for further FTC action, FTC officials have recently announced that they back away from such actions and leave the regulation of Internet pharmacies to state laws and the state attorneys general.⁸⁰

⁷⁶Id. at 12.

⁷⁷*Hearings 2000*, supra note 25, at 15-19.

⁷⁸*Hearings 2001*, supra note 23, at 54.

⁷⁹Federal Trade Commission, *Online Pharmacies Settle FTC Charges*, (viewed February 4, 2002) <<http://www.ftc.gov/opa/2000/07/iog.htm>>.

⁸⁰*Agency Actions*, WASHINGTON INTERNET DAILY, Vol.3., No. 55, March 21, 2002.

IV. Current Regulatory Scheme for of Foreign Internet Pharmacies.

Although regulating and prosecuting domestic Internet pharmacies as operators has proved difficult under existing law, controlling the activities of foreign-based Internet pharmacies has proved nearly impossible due to the lack of U.S. jurisdiction.

Food, Drug and Cosmetic Act. The federal government has the constitutional authority to regulate foreign Internet pharmacies as an aspect of interstate or international commerce. The main source of federal authority to combat foreign Internet pharmacies is the FDCA. With respect to the practices of foreign Internet pharmacies that sell to U.S. customers, The FDCA prohibits the “introduction or delivery for introduction into interstate commerce” of:

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Under these provisions, it would seem that all pharmaceuticals that are imported into the United States are illegal and all foreign Internet pharmacies that send drugs into the U.S. are breaking U.S. law.

Cyber Letters & International Cooperation. Although all foreign Internet pharmacies that sell to U.S. consumers violate these laws, it is effectively impossible for the FDA to pursue these pharmacies. They are beyond the jurisdiction of the United States. Even if the FDA had jurisdiction, it would have difficulty tracking down violators, since the websites do not reveal the operators or the location of the business. In an attempt to deter foreign Internet pharmacies from selling to U.S. citizens, the FDA has resorted to “cyber letters” and international cooperation.

In February 1999, the FDA began sending e-mails to foreign-based pharmacies, warning them that their prescription drug sales to U.S. citizens are illegal. The letters advise the recipients that it is illegal to sell prescription drugs to U.S. citizens without a valid prescription, clarify the FDA’s policy on personal use importation, and warn site operators that packages shipped will automatically be detained at the U.S. border. If the location of the operators can be identified, copies of the warning letters are sent to the FDA’s counterpart in each foreign country, requesting an investigation.⁸⁵ These efforts have produced some results. About 25% of the recipients comply with the request to discontinue illegal dispensing practices.⁸⁶ Of course, that means 75% are ignoring the FDA letters, so while the program may have some effect on deterrent effect, it has hardly been a success. Indeed, even though the FDA sends copies of the warning letters to regulator officials in the countries where the sites are based, the foreign countries do not seem to be responding to the FDA’s concerns. FDA officials recently stated they knew of no instance of a cyber letter prompting a foreign government to shut down a firm or resulting in the imposition of criminal or civil penalties by a

⁸⁵ *Hearings 2000*, supra note 25, at 19 (prepared statement of William K. Hubbard).

⁸⁶ *25% of Cyber Letters Spur Compliance, But Few Cases Concern Drug Counterfeiting*, WARNING LETTER BULLETIN, November 5, 2001.

foreign country.⁸⁷

Obtaining the cooperation of some foreign governments may be possible if U.S. agencies assist foreign agencies in gathering evidence against rogue Internet pharmacies. For example, in 1999, U.S. Customs officials gathered evidence against a Thai Internet pharmacy that exported pharmaceuticals to the U.S. and they worked directly with Thai customs in identifying the operators and pinpointing the location of the operation. In March 2000, this joint operation by U.S. and Thai customs agents led to the arrest of 21 people.⁸⁸ But, even if U.S. regulators work with foreign regulators to obtain information against Internet pharmacies, differences in foreign laws may make such efforts futile. For example, when the New Zealand Ministry of Health tried to enjoin a pharmacist from exporting drugs to U.S. citizens without a prescription, a New Zealand court held that a loophole in the New Zealand federal law lets pharmacists dispense drugs without a prescription to customers outside the country.⁸⁹

Overall, any U.S. attempt to curtail the supply of foreign Internet pharmacies seems futile. Even if some nations have the legislative authority to enjoin foreign sales of pharmaceuticals by businesses in their country, many may not. In the current business climate, many countries, especially developing countries, may be more likely to encourage, rather than discourage, pharmaceutical exports.⁹⁰ It may be impossible for the U.S. to obtain the cooperation of countries that permit the sale of most drugs without prescriptions. And, even if the U.S. is able to obtain the cooperation of some countries to shut certain websites down, the effort will only put a small dent in the supply of foreign Internet pharmacies, since websites will open in countries that do not cooperate with the U.S. government.

Seizures. Since the federal government cannot effectively control the distribution of foreign-source phar-

⁸⁷Id.

⁸⁸Goldman, Charles, *Recent Enforcement and Regulatory Activity Relating to the Internet Pharmaceutical Industry* (visited March 24, 2002) <<http://ebglaw.com>>.

⁸⁹*Pharmacy Law: New Zealand's Legal Loophole*, 133 CANADIAN PHARMACEUTICAL JOURNAL 16 (2000).

⁹⁰Otompke, John. *Internet Likely to Open Brave New World in Global Pharmaceuticals Trade*, MEDICINE & HEALTH, October 9, 2000, at S1.

maceuticals outside its borders, one alternative is to curtail distribution of these goods once they enter the country. Citizens who order misbranded, adulterated, unapproved or reimported pharmaceuticals from rogue Internet pharmacies are also breaking the law. The FDCA provides a criminal enforcement option that would allow a violator to be imprisoned for up to a year or fined up to \$1,000.⁹¹ The FDCA also permits the federal government to refuse admission to illegal pharmaceutical imports.⁹² Although the FDA has the statutory authority to impose criminal penalties on consumers, the FDA has chosen to enforce the FDCA against consumers primarily through seizures. The FDA also has decided not to strictly apply the law against consumers who import pharmaceuticals. In 1954, the FDA developed a “compassionate use” or “personal use policy” regarding the importation of prescription drugs. As originally adopted, this policy permitted U.S. residents to obtain unapproved, foreign-made pharmaceuticals while traveling in a foreign country. In 1988, the policy was amended to allow seriously ill patients to import potentially effective treatments that were not approved for use in the United States. The current official personal use policy of the FDA allows entry of an unapproved prescription drug if:

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⁹¹FDCA §303(a), 21 U.S.C. §333(a) (2002).

⁹²FDCA §801(a), 21 U.S.C. §381(a) (2002).

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Since permissible imports must be for a serious condition for which effective treatment is unavailable in the U.S., this policy has never allowed the importation of foreign versions of U.S.-approved drugs nor reimportations of U.S.-approved drugs.⁹⁴ Unfortunately, this policy has proven difficult to implement.

The seizure of illegal imports requires many levels of coordination between Customs and the FDA. Customs officials identify packages that may violate the FDCA. Customs then refers these packages to the FDA to determine if they are indeed violations and should be detained. If they are detained, the Drug Import Fairness Act requires the FDA to give the importer due process. The FDA must send notice to the addressee explaining the violation and must permit an opportunity for the person to respond. If the addressee does not respond or provides an unsatisfactory response to legitimize the shipment under the FDA's personal use policy for importations, the FDA returns the parcel to Customs and Customs returns the parcel to the sender.⁹⁵

In theory, the FDA's personal use and seizure program seems like a good policy since it allows people with serious illness to obtain alternative treatments and since it protects people from potentially dangerous drugs where a safe treatment exists in the U.S. Unfortunately, due to limited resources, Customs and the FDA are unable to review all packages that enter the U.S. mail system from foreign sources. There are 14 international mail processing facilities, and Customs has difficulty detecting illegal pharmaceutical imports

⁹⁴*Hearings 2001*, supra note 23, at 48 (prepared statement of William Hubbard).

⁹⁵*Id.*

among the tens of millions of parcels passing through the mail facilities each year.⁹⁶ Due to the large volume of incoming packages, Customs is only able to x-ray 10 – 15% of the packages based upon which ones appear to be high risk and they forward the rest to addressees without inspection.⁹⁷ With respect to the packages that Customs detains, the FDA has difficulty reviewing all the packages since there are only 150 inspectors nationwide to analyze the imports.⁹⁸ For example, at one Customs facility that receives several thousand pharmaceutical shipments each week, the FDA only staffs three employees who are able to review about 30 packages a day.⁹⁹ Furthermore, it is impossible for the FDA to conduct forensic testing, or authenticity testing, to ensure the quality of personal imports since such tests costs \$6,000 - \$15,000 per box of drugs.¹⁰⁰ In short, despite the stringent requirements to qualify for the Personal Use Policy for importation, many packages that violate the policy are released to customers, even after a thorough inspection by Customs. According to Elizabeth Durant, an Executive Director of U.S. Customs, “[f]or the most part, if the parcel doesn’t contain a [controlled] substance, it is released back to the Postal Service for delivery.”¹⁰¹ Federal officials estimate that about 200,000 pharmaceutical parcels per month are coming into the U.S. without review.¹⁰²

V. Policy & Proposed Regulations.

Clearly the current regulatory scheme is insufficient to effectively curtail the practices of rogue Internet pharmacies. More legislation, regulation and funding is needed if one believes that these businesses pose an unacceptable risk to the health of Americans.

⁹⁶Id. at 41 (testimony of Elizabeth Durant, Executive Director of Trade Programs at U.S. Customs).

⁹⁷Id. at 72 (testimony of Elizabeth Durant, Executive Director of Trade Programs at U.S. Customs).

⁹⁸Id. at 63 (testimony of William Hubbard).

⁹⁹Id. at 97 (letter from Congressman John Dingell to Bernard Schwetz, Acting Principal Deputy Commissioner, Food and Drug Administration).

¹⁰⁰Id. at 70 (testimony of William Hubbard).

¹⁰¹Id. at 64 (testimony of Elizabeth Durant).

¹⁰²Id. at 9 (prepared statement of Congressman John D. Dingell).

Direct Internet Regulation. The most direct approach to effectively combat illegal Internet pharmacies would be to regulate the Internet directly and prevent these webpages from reaching consumers. The federal or state government could simply filter Internet content itself or require the filtration of Internet content by third parties, such as Internet service providers. This could be done by “blacklisting” or “whitelisting” Internet pharmacy sites. Under blacklisting, access is given to all sites except those listed on the “black” list. Conversely, under whitelisting, access is blocked to all sites except those on the “white” list. The white list could be generated either by humans or by content-examination software. Alternatively, the Internet Corporation for Assigned Names and Numbers (ICANN), a privatized regulatory body which is under contract with the federal government to make policy assigning domain names and web address, could intervene. ICANN could implement a policy disallowing domain names to e-pharmacies that do not meet certain standards. Unfortunately, any one of the above options is likely to be challenged as unconstitutional—a violation of the freedom of speech or as an illegal restraint of trade. Additionally, such regulations are likely to be politically unfeasible in the near future, given the widespread sentiment that the growth of the Internet should not be impeded in any way.

Proposed Federal Legislation. Several bills have recently been proposed in Congress that directly address the problem of Internet pharmacies:

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The adoption legislation similar to that of the Internet Prescription Sales Act will be more effective against curtailing the activities of rogue Internet pharmacies located domestically. As discussed above, the largest impediment to regulating Internet pharmacies located in the U.S. has proven to be the elusiveness of the operators of such sites. The Act does require operators to disclose identifying information, but given the anonymity provided by the Internet, the Act will not make it easier to track down operators who refuse to provide identifying information. Nevertheless, the possibility of a \$500,000 fine may be sufficient to deter most people from engaging in such activities. Even if the probability of being caught is low, the expected fine (i.e., probability of being caught multiplied by the magnitude of the applicable fine) may be high enough to deter such activities. Another virtue of the Internet Prescription Sales Act is that it addresses the problem of lack of resources by federal actors. An additional allocation of funds to the FDA would enable the FDA to identify and bring more actions against illegal Internet pharmacies to enforce existing laws.

Both bills proposed to enable state attorneys general to obtain nationwide injunctions against rogue Internet pharmacies. Allowing nationwide injunctions will be crucial if states are to play a significant role in regulating Internet pharmacies in the future. Under the current regulatory regime, states are wasting resources by engaging in duplicative investigations and prosecutions against out-of-state Internet pharmacies. If action by one state attorney general could preclude an Internet pharmacy from operating or re-opening in other states, this would allow states to allocate their limited resources more efficiently.

Although these proposals are all commendable in their attempts to regulated domestic Internet pharmacies, they fall short in protecting consumers from rogue foreign Internet pharmacies. Neither bill offers a practical solution to the larger problem of foreign Internet pharmacies. The Internet Pharmacy Consumer Act does permit the FDA to enjoin the transfer of funds traceable to illegal transactions, but such actions will be

ineffectual given the ease with which such business can change the name and location of its operations. More drastic legislation is needed if we want to protect consumers from the risk of counterfeit and substandard drugs.

FDA Proposal: Ban All Mail Imports. Recently, the FDA has made a recommendation to the Secretary of Health and Human Services (HHS) that Customs deny entry of all pharmaceuticals imported through the mail and return them to the sender.¹⁰⁵ The policy, however, would retain the current Personal Use Policy, allowing a “minute percentage” of imports to enter for patients with serious diseases to import an unapproved drug from a foreign country.¹⁰⁶ To prevent this exception from rendering the general rule unadministrable, the FDA would require such products to obtain pre-clearance by the FDA and require such parcels to be clearly marked.¹⁰⁷ To enable Customs to seize all incoming pharmaceuticals, Congress would have to repeal the Drug Import Fairness Act, which requires the government to give notice and due process to citizens whose packages are confiscated. According to William Hubbard, an FDA commissioner: “[w]e can’t go through the process that we must now go to, which is to mail a letter to the recipient, receive a response back, and go through that 2 million times.”¹⁰⁸

The FDA proposal appears to be the only way to assure that the federal government can maintain some level of control over the growth of foreign Internet pharmacies that offer their products to U.S. citizens. The policy would not completely eliminate the risk that counterfeit and unsafe drugs are entering the country. Without an allocation of additional resources to U.S. Customs by Congress, Customs will still be unable to x-ray or otherwise analyze every potential pharmaceutical import that passes through its facilities. Nevertheless, this program would allow Customs to seize many more packages than under the current regime.

¹⁰⁵*Hearings 2001*, supra note 25, at 46 (testimony of William Hubbard).

¹⁰⁶*Id.* at 62.

¹⁰⁷*Id.* at 137.

¹⁰⁸*Id.* at 62.

Additionally, a strict rule enforcing seizure if the products are caught will discourage many consumers from ordering drugs from foreign Internet sites to begin with.

Unfortunately, the FDA proposal, standing alone, may be politically unfeasible because it will harm individuals who cannot afford drugs in the United States and who have had to turn to foreign Internet markets. These individuals may be willing to assume the risk of taking counterfeit drugs, since the alternative would be forgoing any treatment at all. One counter argument is that the FDA's proposal does not change the FDA's policy on physical imports. Consumers could still travel across the border to obtain lower-priced drugs in Canada and Mexico, and these practices are safer since consumers actually visit the foreign pharmacy and would be able to return to the store if there is a problem and the foreign government is able to locate the operators. Of course, legislative action would be necessary to address the affordability issues of those who cannot even afford to travel to obtain cheaper medications. A discussion of alternative methods of dealing with this issue beyond the scope of this paper, it is important to point out that addressing Internet pharmacies must be dealt with in tandem with healthcare affordability.

Another problem with the FDA policy is that such an attempt to shut the United States borders to the international pharmaceuticals trade could be deemed a World Trade Organization (WTO) violation. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) requires that measures that restrict trade for precautionary reasons must apply "only to the extent necessary to protect human, animal or plant life or health," be based on scientific principles, and not be maintained without sufficient scientific evidence.¹⁰⁹ The WTO has declared actions similar to a pharmaceutical ban to be in violation of the SPS Agreement. For example, in the mid-1990's, some European nations enacted legislation which banned the importation of hormone-injected beef from the United States. The WTO declared the acts discriminatory because there was a lack of scientific evidence that the hormones posed a substantial health

¹⁰⁹Agreement on the Application of Sanitary and Phytosanitary Measures, art. 2.2, Apr. 15, 1995, MARRAKESH AGREEMENT ESTABLISHING THE WORLD TRADE ORGANIZATION, Annex 1A, Results of the Uruguay Round of Multilateral Trade Negotiations, vol. 1, 69, 70 (1994).

risk.¹¹⁰ Surely the U.S. could generate scientific evidence that counterfeit or adulterated pharmaceuticals pose a substantial health risk to U.S. consumers, however, a country harmed by a U.S. ban on imported pharmaceuticals could argue that the ban is discriminatory and in violation of the SPS Agreement if that country maintains stringent regulations over the quality of its pharmaceutical supply. If the WTO finds such a policy to violate the SPS agreement, it could either require the U.S. to reduce trade barriers in other areas or allow increased trade barriers by the complaining country against the U.S.¹¹¹ Although this discussion only presents a cursory review of the potential international trade issues, it is clear that these issues should be addressed and considered in depth before any policy is adopted.

VII. Conclusion.

The borderless nature of the Internet has challenged and will continue to challenge the regulation of pharmaceuticals in the United States. The most difficult problem has been addressing the problem of foreign based Internet pharmacies and protecting consumers from the counterfeit, unsafe drugs that may be dispensed by these companies. Enacting legislation to address foreign Internet pharmacies may take a long time due to the need to balance the goals of (i) maintaining high standards for the drug supply in the U.S., (ii) ensuring affordability of pharmaceuticals to low-income individuals, and (iii) avoiding overly burdensome regulation of e-commerce and the international marketplace. Perhaps in the meantime, the best approach is to try to reduce consumer demand for such goods by implement public service campaigns to inform consumers as to the dangers of ordering pharmaceuticals from foreign-based pharmacies. In addition to having an effect on consumer demand, these education campaigns may also be effective in rallying the necessary congressional support to address the problem directly, swiftly and comprehensively.

¹¹⁰ Ambrose, Kathleen, *Science and the WTO*, 31 LAW & POL'Y INT'L BUS 861 (2000).

¹¹¹Id.